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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2023-0093]

Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs; Proposed Modifications to Data Collection Fields and Data Validation Procedures; Request for Comment

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain comment on and review of proposed modifications to data collection fields for reporting of pregnancy success rates from assisted reproductive technology (ART) programs and proposed modifications to data validation procedures. This reporting is required by the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA).

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION DATE IN THE **FEDERAL REGISTER**].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2023-0093 by either of the methods listed below.

Do not submit comments by email. CDC does not accept comments by email.

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention,

4770 Buford Highway NE, Mailstop S107–2, Atlanta, Georgia 30341; Attention: Assisted Reproductive Technology Surveillance and Research Team.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to http://regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Mithi Sunderam, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mailstop S107–2, Atlanta, Georgia 30341; Telephone: 1–800–232–4636; Email: ARTinfo@cdc.gov.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. In addition, CDC invites comments specifically on the following modifications to (1) data collection fields for reporting of pregnancy success rates from assisted reproductive technology (ART) programs; and (2) data validation procedures regarding the following proposals in this document:

- CDC proposal to remove the requirement for clinics to report dosage information for fertility medications including Clomiphene, Letrozole, and long-acting FSH.
- CDC proposal to remove the requirement for clinics to report information on research cycle study type.
- CDC proposal to add the requirement for clinics to report date of cryopreservation for fresh embryos.
- CDC proposal not to pursue targeted validation of clinics and identification of

major data discrepancies.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on https://www.regulations.gov. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. **Do not submit comments by email. CDC does not accept comments by email.**

Background

On August 26, 2015, HHS/CDC published a notice in the **Federal Register** (80 FR 51811) announcing the overall reporting requirements of the National ART Surveillance System. This notice described who shall report to HHS/CDC the process for reporting by each ART program; the data to be reported; the process for external validation of clinic data; and the contents of the published reports. CDC has obtained approval from the Office of Management and Budget under the Paperwork Reduction Act to collect this information which is needed to determine the annual pregnancy success rates for each clinic that provides ART services. This data collection is approved under OMB Control Number 0920–0556, expiration date: December 31, 2024. CDC subsequently published a notice in the **Federal Register** on clarifications and modifications on December 15, 2016 (81 FR 90854), and a notice on clarifications and corrections on November 5, 2019 (84 FR 59625). In 2021, CDC published a notice in the **Federal Register** (86 FR 20496) on changes to data validation of ART clinics. Subsequently, CDC published a notice in the

Federal Register on June 10, 2022 (87 FR 35555) that added data collection fields and modified reporting requirements. The purpose of the subject notice is to (1) update data collection fields to reflect changes in ART practice that may impact pregnancy success rates; and (2) update the ART data validation process. This notice provides opportunity for public review and comment for the proposed modifications to data collection fields and data validation procedures.

Proposed Modifications to Data Collection Fields

CDC is currently collecting information on Clomiphene dosage, Letrozole dosage, and other oral medication dosage (80 FR 51811; Section III "What to Report": F "Stimulation and Retrieval"). Clomiphene and Letrozole are established treatment options for ovulation induction and may be administered based on patient diagnostics to increase the chances of ovulation and pregnancy. Other oral medications such as insulin-sensitizing agents may be used in specific groups of patients. Therefore, it is important to monitor the type of medication used, and CDC will continue to collect information on whether Clomiphene, Letrozole or other oral medication were used. However, dosage regimens for these medications follow established guidelines and are less likely to show variability in how they are administered. Given these treatment protocols, collection of these data can be streamlined. In addition, CDC is currently collecting dosage information on long-acting follicle stimulating hormone (FSH) medication. Since this medication is no longer used in ART practice, CDC proposes discontinuing the collection of information on this medication. Therefore, CDC proposes to remove the requirement for ART clinics to report associated dosage information related to (1) Clomiphene, Letrozole, or other oral medication; and (2) long-acting FSH. Deletion: Clomiphene dosage (Total mgs), Letrozole dosage (Total mgs), other oral medication dosage, long-acting FSH (Total mgs).

CDC is currently collecting information on the type of research cycle performed by ART clinics (80 FR 51811; Section III "What to Report": G "Laboratory Information"). Only a small number of research cycles are reported to CDC each year (i.e., 10 cycles in reporting year 2019, 7 cycles in reporting year 2020, and 0 cycles in reporting year 2021). CDC will continue to collect information on whether a cycle can be classified as a research cycle. CDC proposes to remove the requirement for clinics to report the research cycle study type, as only a small number of research cycles are performed each year. Deletion: Research cycle study type – if the cycle was a research cycle. This deletion will apply to all data fields for research study types: Device study, Protocol study, Pharmaceutical study, Laboratory technique, Other research.

CDC is currently collecting information on fresh and frozen-embryo transfer procedures (80 FR 51811; Section III "What to Report": H "Transfer Information"). Embryo stage at the time of transfer is an important predictor of pregnancy success rates. For fresh-embryo transfer procedures, embryo stage can be determined by calculating the difference between the date of transfer and the date of oocyte retrieval. Both dates are currently collected. However, if fresh embryos were cryopreserved instead of being utilized for a fresh transfer, the date of cryopreservation is not currently collected. In recent years, frozen-embryo transfers have become more prevalent as they may improve pregnancy success rates in certain groups of ART patients. For frozen-embryo transfers, the date at which fresh embryos were cryopreserved (with the date of oocyte retrieval) can be used to determine the stage of the embryo at the time of cryopreservation, which is an important predictor of ART success. Therefore, CDC proposes to add the date of fresh-embryo cryopreservation to the currently collected information as it will allow classification of embryo stage for frozen-embryo transfers and improve the reporting of factors that impact ART success rates. Addition: Date fresh embryos were cryopreserved – this date is to be reported for all frozen-embryo transfers.

Proposed Modifications to Data Validation Procedures

Pursuant to the previous FRN notice (86 FR 20496), CDC proposed to conduct targeted validation of ART clinics to better capture systematic reporting errors by assessing certain reporting characteristics that may predict erroneously inflated ART success rates. In addition, CDC proposed to remove a clinic's reported success rates from the annual ART reports if major data discrepancies were identified. Identifying major data discrepancies would require the review of a larger number of clinic records at select clinics, thereby increasing data collection burden for clinics. Given the additional burden, CDC will not pursue implementation of targeted validation of ART clinics and identification of major discrepancies during data validation. CDC will continue to calculate discrepancy rates for key variables and provide feedback to clinics to improve the reporting of data used to report success rates as described in the FRN notice (80 FR 51811). In addition, CDC will continue removing a clinic's reported success rates from annual ART reports if the clinic was selected for annual ART data validation but declined to participate as described in the FRN notice (86 FR 20496).

Tiffany Brown,
Executive Secretary,
Centers for Disease Control and Prevention.

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